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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,968	01/25/2002	James Peter Burnie	. P 0290403	8442

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EXAMINER

WINKLER, ULRIKE

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/054,968

Applicant(s)

BURNIE ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Preliminary Amendment filed October 17, 2002 (Paper No. 11) is acknowledged and has been entered. Claims 1-41 have been cancelled. Claim 42 has been added and is currently being examined.

Specification

The abstract of the disclosure is objected to because. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. Correction is required. See MPEP § 608.01(b).

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 42 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating mice with serum obtained from patients that have recovered from septicemia, does not reasonably provide enablement for the treatment of using antibodies or fragments thereof to immunogenic fragments of an ABC transporter and fragments having the sequence of SEQ ID NO: 6, 7 and 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant claims evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is drawn to treatment method of a human or an animal with a neutralizing agent (an antibody) that is specific for a bacterial ABC transporter protein or immunogenic fragment thereof. The state of the prior art is such that using antibodies for bacterial treatment methods (a.k.a. serum therapies) have been known since before the advent of antibiotics (see Casadevall et al., *Clinical Infectious Diseases*, 1995, Vol. 21, pp. 150-161). However, there is unpredictability in the prior art as to determining what fragments of a protein may stimulate beneficial immune responses, Paul (*Fundamental Immunology*, Raven Press, New York, NY; 1993, 3rd Edition, pg. 251, column 1, lines 11-12) states that immunogenicity is limited by self-tolerance, and that the repertoire of potential antigenic sites in a given

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polypeptide is a specific for the host organism. Klein ("Self-nonsel discrimination, histoincompatibility, and the concept of immunology", Immunogenetics, 1999, Vol. 50, No. 3-4, pages 116-123) teaches that the property of immunogenicity for a polypeptide is based upon the recognition of said polypeptide as a "non-self" polypeptide. The discrimination between self and non-self proteins do not rely on simple qualitative features of the amino acid sequences in question, and that foreign, "non-self" peptides, known not to be present in humans, can mimic "self" antigens and thus can be tolerated (non-immunogenic) within the host. Therefore, it would be difficult to predict what peptides an "epitope" would consist of having only the amino acid sequence of the polypeptide. The guidance present in the specification is insufficient for the scope of the invention. The specification teaches that in a patient recovering from septicemia caused by *E. faecium* produces antibodies that are reactive with four immunodominant bands 97, 57, 54 and 40 kDa. The specification has also teaches epitope mapping of SEQ ID NO:2, which revealed 1 generic epitope and 5 specific epitopes. Therefore, it is unpredictable that an immunogenic fragment comprising these sequences will be specific for bacterial ABC transporters and thereby useful for antibacterial treatment. The specification, fails to show a direct correlation of antibodies that bind the specific epitope and amelioration of the disease state thereby constituting a therapy. The only experimental evidence provided in the specification shows the recovery of mice which have been treated with human serum from patients that have recovered from septicemia. These serum samples contain additional antibodies that are not specific to the epitopes in question but also to other undisclosed epitopes that do not recognize the ABC transporter. Therefore, from the observations made in the experiments one of ordinary skill in the art cannot conclude that antibodies to fragments of an ABC transporter protein will

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have efficacy required for treatment purposes. Therefore, applicant is inviting artisan to perform undue experimentation and the specification is not enabled for the full scope of the invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Conclusion

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.